

09/779,334

Attorney Docket No.: 6092.200-US

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Sjöholm et al

Confirmation No: 9041

Serial No.: 09/779,334

Group Art Unit: 1651

Filed: February 8, 2001

Examiner: Jon Weber

For: Use of Acid Stable Protease in Animal Feed

**AMENDMENT UNDER 37 C.F.R. 1.111**

Commissioner for Patents  
Washington, DC 20231

Sir:

In response to the Office Action mailed August 6, 2002, please amend the above-identified application as follows (a marked up version pursuant to 37 C.F.R. 1.21 is attached hereto):

**IN THE SPECIFICATION:**

Please replace the paragraph on page 3, lines 18-23 with:

Included in the above definition of protease are any enzymes belonging to the EC 3.4 enzyme group (including each of the thirteen sub-subclasses thereof) of the EC list (Enzyme Nomenclature 1992 from NC-IUBMB, 1992), as regularly supplemented and updated.

Please replace the paragraph on page 13, lines 16-17 with:

Further, optional, feed-additive ingredients are colouring agents, aroma compounds, stabilisers, and/or at least one other enzyme selected from amongst phytases EC 3.1.3.8 or 3.1.3.26; xylanases EC 3.2.1.8; galactanases EC 3.2.1.89; and/or beta-glucanases EC 3.2.1.4 (EC refers to Enzyme Classes according to Enzyme Nomenclature 1992 from NC-IUBMB, 1992).

Please replace the paragraph on page 39, lines 15-22 with:

SSI was purified from a *Streptomyces albobogiseolus* FERM P 1205 (S-3253) fermentation supernatant by chromatography. The used SSI preparation had a purity above 95% - the purity

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was determined by the procedure described in Example 2A. Alternatively, SSI can be obtained from Wako in Japan, catalog no. 303-05201, manufactured by Daiwa Kasei K.K.

**IN THE CLAIMS:**

Please cancel claims 1-10 and 13 without prejudice or disclaimer. Please add claims 14-22:

14. An animal feed additive comprising (a) at least one purified acid-stable protease and (b) one or more fat soluble vitamins, water soluble vitamins, and trace minerals, wherein the protease is of the subtilisin family and/or has less than 10% residual activity when inhibited with a molar excess *Streptomyces* subtilisin inhibitor.

15. The animal feed additive of claim 14, wherein the amount of the purified protease corresponds to 0.01-200 mg protease protein per kg feed.

16. The animal feed additive of claim 14, wherein the protease is a *Bacillus*, NCIMB 40484 protease.

17. An animal feed composition having a crude protein content of 50-800 g/kg comprising the animal feed additive of claim 14 and a vegetable protein or protein source.

18. The animal feed composition of claim 17, which further comprises at least one enzyme selected from the group consisting of phytase, xylanase, galactanase, and beta-glucanase.

19. The animal feed composition of claim 17, wherein the protease is a *Bacillus*, NCIMB 40484 protease.

20. A method for the improving the nutritional value of a vegetable protein or protein source, comprising adding an animal feed additive of claim 14 to the vegetable protein or protein source.

21. The method of claim 20, wherein the vegetable protein comprises soybean.

22. The method of claim 20, wherein the protease is a *Bacillus*, NCIMB 40484 protease.

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**REMARKS**

Claims 1-10, and 13, have been cancelled without prejudice or disclaimer. Claim 14-22 have been added and therefore pending in the present application. Claims 14-22 are supported by original claims 1-12.

The specification has been amended to delete the hyperlinks, as requested by the Examiner.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

**I. The Restriction Requirement**

The Office maintained the restriction requirement between the following groups:

Group I – claims 1-5 and 9-10 drawn to animal feed comprising protease and methods of making;

Group II – claims 6-7 drawn to feed additives comprising protease; and

Group III – claims 8 and 13 drawn to feed additives comprising protease and glucanase.

The restriction requirement is respectfully traversed.

The test for determining whether inventions which are related as combination and subcombination are distinct and therefore subject to a restriction requirement is set forth in the Manual of Patent Examining Procedures, section 806.05(c). The two prongs of the test are that "(1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) the subcombination has utility by itself or in other combinations." Both prongs must be satisfied in order for these related inventions to be distinct.

In the present case, the claims to the combination (i.e., feed compositions) contain all of the limitations of the claims to the subcombination (i.e., feed additives). Therefore, the first prong of the above test is not met and, therefore, restriction is improper.

Moreover, Applicants submit that the claims drawn to feed additives link inventions I, II and III. Therefore, upon allowance of the linking claim, the restriction requirement as to the linked inventions should be withdrawn and all claims should be examined in the instant application.

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**II. The Rejection of Claims 6 and 7 under 35 U.S.C. 112**

Claims 6-7 are rejected under 35 U.S.C. 112 as failing to provide an adequate written description of the invention, failing to provide an enabling disclosure, and failing to present the best mode contemplated without complete evidence of the deposit of the biological material.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants enclose a Statement UNDER 37 C.F.R. 1.808, as requested by the Examiner. Applicants therefore submit that this rejection has been overcome.

**III. The Objection to Claim 6**

The Office objected to claim 6 because of the informality of not spelling out the abbreviated term SSI. The abbreviation SSI has been spelled out in the new claim 14, supported by the description page 4, lines 16-20.

For the foregoing reasons, Applicants submit, that this objection has been overcome.

**IV. The Rejection of Claims 6-7 under 35 U.S.C. 102**

Claims 6-7 are rejected under 35 U.S.C. 102 as being anticipated by Van Heyningen et al. (1971), Van Heyningen (1972), Outtrup et al. (US 5,597,720), Ichishimia et al. (US 4,480,037); Horikoshi et al. (US 4,052,262); Boguslawski et al. (US 4,429,044); Lehmann et al. (US 4,062,732); and Schindler et al. (US 4,473,644). These rejections are respectfully traversed.

These references disclose various proteases.

However, none of the references disclose an animal feed additive or composition comprising a purified acid-stable protease and at least one compound selected from the group consisting of fat-soluble vitamins, water-soluble vitamins, and trace minerals.

For the foregoing reasons, Applicants submit that the claims overcome these rejections under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejections.

**V. The Rejection of Claims 6-7 under 35 U.S.C. 102 and 103**

Claims 6-7 are rejected under 35 U.S.C. 102 as being anticipated by, or in the alternative, as obvious over Aunstrup et al. (US 3,674,643). These rejections are respectfully traversed.

Aunstrup et al. disclose various proteases.

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However, Aunstrup et al. also do not disclose or suggest animal feed additives or compositions comprising a purified acid-stable protease, and at least one compound selected from the group consisting of fat-soluble vitamins, water-soluble vitamins, and trace minerals.

For the foregoing reasons, Applicants submit that the claims overcome the rejections under 35 U.S.C. 102 and 103. Applicants respectfully request reconsideration and withdrawal of the rejections.

#### VI. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Sir:

Below is a marked-up version of the amendments made in the accompanying amendment.

**IN THE SPECIFICATION:**

The paragraph on page 3, lines 18-23 has been amended as follows:

Included in the above definition of protease are any enzymes belonging to the EC 3.4 enzyme group (including each of the thirteen sub-subclasses thereof) of the EC list (Enzyme Nomenclature 1992 from NC-IUBMB, 1992), as regularly supplemented and updated, ~~see e.g. the~~ ~~World Wide Web (WWW) at~~ http://www.chem.gmw.ac.uk/iubmb/enzyme/index.html.

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Further, optional, feed-additive ingredients are colouring agents, aroma compounds, stabilisers, and/or at least one other enzyme selected from amongst phytases EC 3.1.3.8 or 3.1.3.26; xylanases EC 3.2.1.8; galactanases EC 3.2.1.89; and/or beta-glucanases EC 3.2.1.4 (EC refers to Enzyme Classes according to Enzyme Nomenclature 1992 from NC-IUBMB, 1992); ~~see also the World Wide Web (WWW) at~~ http://www.chem.gmw.ac.uk/iubmb/enzyme/index.html.

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was determined by the procedure described in Example 2A. Alternatively, SSI can be obtained from Wako in Japan, catalog no. 303-05201, manufactured by Daiwa Kasei K.K. (see eg: <http://search.wako-chem.co.jp/lifedb-e/lifedocs-e/44834.asp>).